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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,819	11/06/2000	Akira Aomatsu	5774-01-MJA	5038

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EXAMINER	
WESSENDORF, TERESA D	

ART UNIT	PAPER NUMBER
1639	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/674,819	AOMATSU, AKIRA	
	Examiner	Art Unit	
	T. D. Wessendorf	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28,35-37,40,41 and 43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28,35-37,40,41 and 43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments in the Appeal Brief filed on 5/4/2007 have been considered but are moot in view of the new ground(s) of rejection below.

Status of Claims

Claims 28, 35-37, 40-41 and 43 are pending and under examination.

Priority

If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 119(e), a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. See MPEP § 201.11.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point

out and distinctly claim the subject matter which applicant regards as the invention.

1. Non-sequitur for "the form of..." in claim 40.

2. Claim 43 appears to be drawn more to a process claim rather than a composition claim. Non-sequitur for "the content of the corresponding lactam" and "the initial amount".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the

reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

> (f) he did not himself invent the subject matter sought to be patented.
>
> (g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 28, 36, 40-41 and 43 are rejected under 35 U.S.C. 102(e) as being anticipated by Lan (20020037926). (See the Schrier rejection below with respect to applicants' priority claim).

Lan discloses at paragraph:

[0028] Gabapentin and pregabalin can be formulated to provide greater stability to the compound. Useful excipients for inclusion with gabapentin and pregabalin include neutral amino acids, such as glycine and L-valine; and humectants, such as ethylene glycol, propylene glycol and glycerine. The active compounds may also be coated as agglomerated powders with a polymer such as polyvinyl pyrrolidone to provide better stability and processing characteristics.

Claims 28, 36, 40 and 41 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative under 35 U.S.C. 103(a) as obvious over Schrier et al. (WO 98/58,641).

For claim 28, Schrier et al disclose a composition of pregabalin (pg. 3, lines 19-22). The composition comprise the active compound, pregabalin in dosage unit forms with a pharmaceutical carrier (see e.g. pg. 4, line 17 thru pg. 5, line 11). The pharmaceutical carrier includes pharmaceutical propylene glycol and sorbitol (see e.g. pg. 4, lines 22-28).

For claim 36, Schrier et al. disclose that the composition also include other component such as coloring agents, flavoring agents, and/or preservatives (refers to instant claimed an auxiliary agent)(see e.g. pg. 4, line 31 thru pg. 5, line 2).

For claim 40, Schrier et al. disclose that the dosage unit forms include tablets, capsules and pills (see e.g. pg. 4, lines 19-22).

For claim 41, Schrier et al. disclose that the compositions are produced by formulating the active compound in dosage unit form with a pharmaceutical carrier that include diluent (see e.g. pg. 4, lines 17-31).

The claimed property of the composition i.e., a stabilized composition is inherent to the composition of Schrier since Scheier discloses the same composition as claimed.

> Where the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See In re Ludtke, supra. Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same as is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. See In re Brown, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972); In re Best 195 USPQ 430 (CCPA 1977).

Applicant is not entitled to the priority date of the Japanese foreign patent in the absence of an English translation. The provisional application also relied for its earlier filing date does not disclose the pregabalin derivative. It appears that said Japanese foreign application corresponds to the provisional application and thus does not also disclose pregabalin. (Note the provisional and Japanese application contain only 24 pages compare to the instant specification of 75 pages). Said pregabalin is disclosed only in the PCT application filed on 5/10/99. Thus, the Schrier reference (Dec. 30, 1998) predates the instant PCT application filing date with respect to pregabalin and therefore is a proper reference.

Claims 28, 36, 40 and 41 are rejected under 35 U.S.C. 102(f or g) as anticipated by or, in the alternative under 35 U.S.C. 103(a) as obvious over Schrier et al (USP 6,329,429).

Applicant appears not to have invented the instant claimed composition as evident from the Schrier et al patent.

See above rejection.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned US Patent 6,329,429, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 28, 36, 40 and 41 are rejected on the ground of nonstatutory double patenting over claims 1 and 8 of U. S. Patent No. 6, 329,429 since the claims, **if allowed, would improperly extend the "right to exclude" already granted in the patent.**

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: the instant claimed composition is disclosed by Schrier, (see equivalent WO 98/58,641) above, as used in the claimed method by Schrier.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claims 28, 35-37, 40-41 and 43 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wallace (US 5,025,035) or 5,084,479 (Woodruff).

Wallace and Woodruff disclose compositions of gabapentin and other 4-amino-3-substituted-butanoic acid derivatives with propylene glycol; see col. 2, lines 13-57 of Wallace and Example 3. See Woodruff at col. 3, line 35 to col. 4, line 12.

See the above rejection under Schrier (WO 98/58641).

Claim Rejections - 35 USC § 103

Claims 28, 35-37, 40-41 and 43 are rejected under 35 U.S.C. 103(a) as being obvious over Augart et al (US 6,054,482)

in view of any one of Giacin (US5302373), Herget (US5618342) or Baschang (4666886).

Augart et al(US'482, hereafter) teach a stable solid composition in the form of tablet or capsules(dry medicinal forms) and a process for the preparation thereof, wherein the composition comprises a cyclic amino derivative of the general formula I such as gabapentin as an active agent and an adjuvant materials (e.g. polyethylene glycol), see abstract, col. 2, lines 27-30, claims (especially, claim 4, (c) and claim 8) and column 3 lines 25-45. It is noted that the specific adjuvants of US'482(i.e., polyethylene glycol) are conventionally known as humectants and naturally play the role as "humectant" that is any substance added to another substance to keep the moisture. Any compound of the said adjuvants of US'482 would be used to prevent the excess water available for forming undesirable lactam. Thus, the cited reference discloses that said compounds (e.g., polyethylene glycol) carry out the stabilization of the active agent from lactam formation whether they are called humectant or not. For instance, the stabilizing activity carried out by the said compounds is enabled in US'482 wherein the formation of lactam (byproduct) that is usually associated with certain toxicities can be suppressed by the preferred adjuvants (e.g., polyethylene glycol, see column 4, lines 60 thru column

5, lines 33). Augurt does not disclose one of the glycols i.e, propylene glycol as claimed. However, Herget or anyone of the above secondary references discloses the functional equivalence of propylene and ethylene glycol as humectant.

US'373 teaches that propylene glycol, glycerol, sorbitol, or cyclodextrin is functionally equivalent humectant, see column 2, lines 28-33.

US'342 teaches that glycerol, substituted glycerol, sorbitol, polyethylene glycol, polypropylene glycol, polyvinylpyrrolidone is functional equivalent humectant, see claim 3.

Baschang discloses at e.g., col. 25, lines 63-65:

> Ointments are water-in-oil emulsions that contain up to 70%, but preferably from approximately 20% to approximately 50%, of water or aqueous phase. As fatty phase there come into consideration especially hydrocarbons, for example petroleum jelly, paraffin oil and/or hard paraffins, which, in order to improve the water-binding capacity, preferably contain suitable hydroxy compounds, such as fatty alcohols or esters thereof, for example cetyl alcohol or wool wax alcohols, or wool wax. Emulsifiers are corresponding lipophilic substances, such as sorbitan fatty acid esters (Spans), for example sorbitan oleate and/or sorbitan isostearate. Additives to the aqueous phase are, inter alia, humectants, such as polyalcohols, for example glycerine, propylene glycol, sorbitol and/or polyethylene glycol, and also preservatives, perfumes etc.

Accordingly, it would have been obvious to one having ordinary skill in the art to substitute the polyethylene glycol in the composition of Augurt with another glycol as the

homologous propylene glycol, as taught by any one of the secondary references e.g., Herget or Baschang. One having ordinary skill in the art would reasonably expect to successfully obtain the same stable compositions due to the known functional equivalence of these glycols as taught by anyone of the numerous prior art cited by applicants. When the teaching of each reference(individually or in combination) is taken together with US'482, it would have been readily apparent to the one of ordinary skill in the art to envision the term substitution where the adjuvants can be substituted with the term, humectant where polyethylene or propylene glycol is effectively preventing the lactam formation via suppressing catalysis as suggested by US'482 at column 4 and claim 3(c). One would have motivated to do so, with reasonable expectation of success, because the humectants(i.e, polyethylene or propylene glycol) can effectively absorb the excessive water that is required for the lactam formation so that the water would not be available for lactam formation. One would have been motivated to modify the reference and have expected reasonable success, because they are drawn to same technical fields (constituted with same ingredients(e.g., polyethylene or propylene glycol) and share common utilities(i.e., activity of the humectant to suppress

lactam formation), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on 571 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

T. D. Wessendorf
Primary Examiner
Art Unit 1639

Tdw
August 18, 2007